

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: )  
 )  
Gary K. Michelson )  
 )  
Serial No.: (Cont. of 09/626,636) ) (Group Art Unit: 3731)  
 )  
Filed: September 18, 2003 ) (Examiner: U. Ho)  
 )  
For: OSTEOGENIC PACKING DEVICE) )  
AND METHOD )

Mail Stop PATENT APPLICATION  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Sir:

**INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(b)**

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(b), applicant brings to the attention of the Examiner the documents listed on the attached Form PTO-1449. This Information Disclosure Statement is being filed concurrently with the above-referenced application.

Copies of the listed documents including any English language abstracts/translations were previously cited in a prior application, Serial No. 09/626,636, filed July 27, 2000; Serial No. 08/484,927, filed June 7, 1995 (now U.S. Patent No. 6,096,038); and/or Serial No. 08/074,781, filed June 10, 1993 (now U.S. Patent No. 5,484,437), upon which applicant relies for the benefits provided in 35 U.S.C. § 120.

Please note that ES 283078 is related to U.S. Patent No. 4,877,020; JP 57-29348 is related to U.S. Patent No. 4,349,921; and JP 61-122859 is related to U.S. Patent No. 4,759,766. Additionally, the following U.S./U.K. patents are related to the following non-English references:

GB 1291470	relates to	DE 1961531
GB 1492990	relates to	DE 2446039
GB 1531487	relates to	FR 2295729
US 5,279,292	relates to	DE 4104359

Applicant respectfully requests that the Examiner consider the listed documents and indicate that they were considered by making appropriate notations on the attached form.

The present application is a continuation of Serial No. 09/626,636, filed July 27, 2000; which is a continuation application of Serial No. 08/484,927, filed June 7, 1995 (now U.S. Patent No. 6,096,038); which is a divisional application of Serial No. 08/074,781, filed July 10, 1993 (now U.S. Patent No. 5,484,437). The '781 application is a continuation-in-part application of Serial No. 07/968,240, now U.S. Patent No. 5,741,253, which is a continuation of application Serial No. 07/698,674, now abandoned, which is a divisional application of Serial No. 07/205,935, now U.S. Patent No. 5,015,247.

Applicant brings to the Examiner's attention that the '247 patent was the subject of litigation in the United States District Court for the Central District of California, Western Division, Civil Action No. 95-0258RG, hereinafter referred to as Litigation 1. The claims of the '247 patent are directed to a fusion implant.

The '253 patent was the subject of litigation in the United States District Court for the Western District of Tennessee, Civil Action No. 98-2369GA (JSG), hereinafter referred to as Litigation 2. The '253 patent was also the subject of litigation in the United States District Court for the Western District of Tennessee, Western Division, Case No. 99-2656GV, hereinafter referred to as Litigation 3 ("Lit. 3"). The claims of the '253 patent are generally directed to a method for preparing adjacent vertebrae to receive an implant.

The '437 patent and U.S. Patent No. 6,096,038 (a divisional of the '437 patent) were also the subject of litigation in Litigation 3. The claims of the '437 patent are generally directed to a method for inserting an implant. The claims of the '038 patent are generally directed to instruments used for preparing adjacent vertebrae to receive an implant and/or inserting an implant.

In Litigations 1-3, the defendants asserted that various references were pertinent to the issue of validity of the '247 patent, the '253 patent, the '437 patent, and the '038 patent under 35 U.S.C. §§ 102 and 103. Applicant notes for the Examiner on the attached Form PTO-1449 in the column for the Examiner's initials the references identified by defendants in Litigation 1 as being allegedly pertinent to the '247 patent by the designation "Lit. 1." References identified by the defendants in Litigation 2 as being allegedly pertinent to the '253 patent are identified by the designation "Lit. 2." References identified by the defendants in Litigation 3 as being allegedly pertinent to the '437 patent are identified by the designation "Lit. 3a." References identified by defendants in Litigation 3 as being allegedly pertinent to the '253 patent are identified by the designation "Lit. 3b." References identified by defendants in Litigation 3 as being allegedly pertinent to the '038 patent are identified by the designation "Lit. 3c."

The defendants in Litigation 3 also raised allegations of inequitable conduct in relation to the procurement of:

(1) the '253 patent for failing to (a) highlight U.S. Patent No. 4,570,624 to Wu, (b) disclose litigation related to the '247 patent, and (c) disclose EP 0077159 to Atkins, an article written by Jose Vich ("Anterior cervical interbody fusion with threaded cylindrical bone," *Neurosurg* 63: 750-753, 1985), and manuals by Muller, M.E. ("Manual of Internal Fixation: Techniques Recommended by the AO Group;" Second Edition, Expanded and Revised; pp. 3-20, 27-41, 53-58, 71-78, 94, 311, 320; Springer-Verlag; 1979), Hierholzer, G. ("Manual on the AO/ASIF Tubular External Fixator;" pp. 85-91; Springer-Verlag; 1985), and Heim, Urs ("Small Fragment Set Manual: Technique Recommended by the ASIF-Group;" pp. 5-7, 10, 20, 21, 30; Springer-Verlag; 1974);

(2) the '437 patent for failing to (a) disclose the existence of and information surrounding litigation concerning inventorship issues with the subject matter of U.S. Patent No. 5,489,307 to Kuslich and (b) disclose U.S. Patent No. 2,842,131 to Smith, U.S. Patent No. 4,142,517 to Stavropoulos et al., U.S. Patent No. 4,677,883 to Lee, U.S. Patent No. 4,830,000 to Shutt, U.S. Patent No. 4,878,915 to Brantigan, U.S. Patent No. 4,943,291 to Tanguy, U.S. Patent No. 4,961,740 to Ray et al., and U.S. Patent No. 5,055,104 to Ray; and

(3) the '038 patent for failing to (a) disclose the existence of and information surrounding litigation concerning inventorship issues with the subject matter of U.S. Patent No. 5,489,307 to Kuslich and (b) filing an allegedly misleading Rule 131 declaration.

Litigations 1-3 are no longer pending. The jury in Litigation 2 found all asserted claims of the '253 patent valid in view of the art cited by the defendant. Litigations 1-3 were settled with the defendants in each litigation retracting their assertions of invalidity and inequitable conduct. Discovery documents relating to the aforementioned litigations are available upon request.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If the Examiner applies any of the documents as prior art against any claim in the application and applicant determines that the cited documents do not constitute "prior art" under United States law, applicant reserves the right to present to the office the relevant facts and law regarding the appropriate status of such documents.

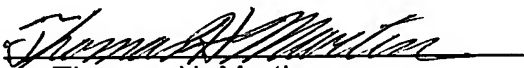
Applicant further reserves the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

If there is any fee due in connection with the filing of this Statement, please charge the fee to our Deposit Account No. 50-1068.

Respectfully submitted,

MARTIN & FERRARO, LLP

Date: September 18, 2003

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<b>Substitute for FORM PTO-1449</b>	<b>Attorney Docket Number</b> 102.0003-09000	<b>Customer No.</b> 22882	
<b>INFORMATION DISCLOSURE CITATION IN AN APPLICATION</b>	<b>Applicant</b> Gary K. Michelson	<b>Application Number</b> (Cont. of 09/626,636)	
	<b>Filing Date</b> September 18, 2003	<b>Group Art Unit</b> (3731)	<b>Examiner</b> (U. Ho)

**U.S. PATENT DOCUMENTS**

Examiner Initial*	Document Number	Date	Name	Class	Sub Class	Filing Date If Appropriate
	Des. 245,259	08/1977	Shen			
	Des. 257,511	11/1980	Zahn			
	Des. 260,525	09/1981	Lassiter			
	Des. 281,814	12/1985	Pratt et al.			
	Des. 318,629	07/1991	Michelson			
Lit. 1	Re. 31,865	04/1985	Roux			
	350,420	10/1886	Dillon			
	493,730	03/1893	MacKenzie			
	640,108	12/1899	Dalzell			
	1,137,585	04/1915	Craig			
	2,065,659	12/1936	Cullen			
	2,181,746	11/1939	Siebrandt			
	2,243,718	05/1941	De G. Moreira			
	2,372,622	03/1945	Fassio			
	2,514,665	07/1950	Myller			
	2,537,070	01/1951	Longfellow			
	2,543,780	03/1951	Hipps et al.			
	2,677,369	05/1954	Knowles			
	2,774,350	12/1956	Cleveland			
	2,789,558	04/1957	Rush			
	2,832,343	04/1958	Mose			
	2,842,131	07/1958	Smith			
	2,878,809	03/1959	Treace			

Lit. 2	3,128,768	04/1964	Geistauts			
Lit. 1	3,298,372	01/1967	Feinberg			
	3,426,364	02/1969	Lumb			
Lit. 2	3,486,505	12/1969	Morrison			
Lit. 1	3,604,487	09/1971	Gilbert			
	3,605,123	09/1971	Hahn			
	3,618,611	11/1971	Urban			
	3,709,219	01/1973	Halloran			
Lit. 3b	3,719,186	03/1973	Merig, Jr.			
	3,720,959	03/1973	Hahn			
	3,750,652	08/1973	Sherwin			
Lit. 2	3,848,601	11/1974	Ma et al.			
	3,855,638	12/1974	Pilliar			
	3,867,728	02/1975	Stubstad et al.			
	3,867,950	02/1975	Fischell			
Lit. 2	3,875,595	04/1975	Froning			
	3,877,020	10/1989	Vichl			
	3,888,260	06/1975	Fischell			
Lit. 2	3,892,232	07/1975	Neufeld			
Lit. 1	3,905,047	09/1975	Long			
	3,915,151	10/1975	Kraus			
	3,916,907	11/1975	Peterson			
	3,918,440	11/1975	Kraus			
	3,942,535	03/1976	Schulman			
	3,948,262	04/1976	Zaffaroni			
	3,952,334	04/1976	Bokros et al.			
	3,987,499	10/1976	Scharbach et al.			
Lit. 1	4,016,651	04/1977	Kawahara et al.			
	4,027,392	06/1977	Sawyer et al.			
	4,051,905	10/1977	Kleine			
	4,059,115	11/1977	Jumashev et al.			
	4,070,514	01/1978	Entherly et al.			

	4,082,097	04/1978	Mann et al.			
Lit. 1	4,086,701	05/1978	Kawahara et al.			
Lit. 1	4,124,026	11/1978	Berner et al.			
	4,142,517	03/1979	Stravropoulos et al.			
	4,168,326	09/1979	Broemer et al.			
Lit. 1	4,175,555	11/1979	Herbert			
Lit. 1	4,177,524	12/1979	Grell et al.			
	4,181,457	01/1980	Holmes			
	4,197,850	04/1980	Schulman et al.			
	4,206,516	06/1980	Pilliar			
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Lit. 1	4,259,072	03/1981	Hirabayashi et al.			
Lit. 1	4,262,369	04/1981	Roux			
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	4,289,123	09/1981	Dunn			
Lit. 1	4,293,962	10/1981	Fuson			
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Lit. 1	4,328,593	05/1982	Sutter et al.			
	4,333,469	06/1982	Jeffcoat et al.			
	4,341,206	07/1982	Perrett			
Lit. 1 & 3c	4,349,921	09/1982	Kuntz			
Lit. 1	4,356,572	11/1982	Guillemin et al.			
	4,401,112	08/1983	Rezaian			
	4,405,319	09/1983	Cosentino			
	4,414,979	11/1983	Hirshorn et al.			
	4,423,721	01/1984	Otte et al.			
	4,439,152	03/1984	Small			
	4,450,834	05/1984	Fischer			

Lit. 1	4,484,570	11/1984	Sutter et al.			
	4,492,226	01/1985	Belykh et al.			
	4,497,320	02/1985	Nicholson et al.			
Lit. 1 & 2	4,501,269	02/1985	Bagby			
	4,507,115	03/1985	Kambara et al.			
	4,530,360	07/1985	Duarte			
	4,535,374	08/1985	Anderson et al.			
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	4,542,539	09/1985	Rowe, Jr. et al.			
Lit. 2	4,545,374	10/1985	Jacobson			
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	4,552,200	11/1985	Sinha et al.			
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	4,554,914	11/1985	Kapp et al.			
	4,570,623	02/1986	Ellison et al.			
Lit. 2, 3b, & 3c	4,570,624	02/1986	Wu			
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	4,599,086	07/1986	Doty			
	4,600,000	07/1986	Edwards			
	4,602,638	07/1986	Adams			
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	4,611,581	09/1986	Steffee			
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	4,645,503	02/1987	Lin et al.			
Lit. 1	4,653,486	03/1987	Coker			
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	4,698,375	10/1987	Dorman et al.			
	4,710,075	12/1987	Davison			
Lit. 1	4,713,004	12/1987	Linkow et al.			
Lit. 3c	4,714,469	12/1987	Kenna			
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	4,736,738	04/1988	Lipovsek et al.			
Lit. 1 & 2	4,743,256	05/1988	Brantigan			
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	4,759,766	07/1988	Buettner-Janz et al.			
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	4,805,602	02/1989	Puno et al.			
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	4,830,000	05/1989	Shutt			
Lit. 1 & 2	4,834,757	05/1989	Brantigan			
Lit. 2	4,848,327	07/1989	Perdue			
	4,851,008	07/1989	Johnson			
Lit. 2	4,863,476	09/1989	Shepperd			
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Lit. 1	4,877,020	10/1989	Vich			

Lit. 1 & 2	4,878,915	11/1989	Brantigan			
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Lit. 3a & 3c	5,055,104	10/1991	Ray			
	5,059,193	10/1991	Kuslich			
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	5,071,437	12/1991	Steffee			
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	5,192,327	03/1993	Brantigan			
	5,246,458	09/1993	Graham			
	5,258,031	11/1993	Salib et al.			
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Lit. 3a & 3c	5,489,307	02/1996	Kuslich et al.			
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	5,105,819	04/1992	Wollschlager, et al.			
	5,505,732	04/1996	Michelson			

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	Document Number	Date	Country	Class	Sub Class	Translation Yes or No
Lit. 2, 3a, 3b & 3c	0 077 159	04/1983	Europe			N/A
	0 162 005	11/1985	Europe			Yes
	0 260 044	03/1988	Europe			N/A

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	0 307 241	03/1989	Europe			N/A
	0421485 A1	10/1998	Europe			N/A
	0499465 A1	08/1992	Europe			N/A
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	0627204 A2	12/1994	Europe			Abstract Only
	0 179 695	04/1986	France			Abstract and Partial
	2 295 729	07/1976	France			UK Equivalent GB 1531487
	2 581 336	11/1986	France			Abstract Only
	2 703 580	10/1994	France			Yes
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	DE 41 04 359 A1	08/1992	Germany			US Equivalent 5,279,292
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	GB 1492990	11/1977	Great Britain			N/A
	GB 1531487	11/1978	Great Britain			N/A
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	61-122859	06/1986	Japan			US Equivalent 4,759,766
	62-155846	07/1987	Japan			Yes

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	91/06266	05/1991	PCT			N/A
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	93/01771	02/1993	PCT			N/A
	1063397	12/1983	Soviet Union			Yes
	1107854	08/1984	Soviet Union			Yes
	1124960	11/1984	Soviet Union			Abstract Only
	1217374	03/1986	Soviet Union			Abstract Only
	1222254	04/1986	Soviet Union			Abstract Only
Lit. 1	283078	05/1985	Spain			US Equivalent 4,877,020
	106 101	07/1939	Sweden			Partial
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>						
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	Gillingham, F.J., et al.; Head injuries; Proceedings of the 18 <sup>th</sup> World Congress of the International College of Surgeons, Rome, pp. 68-71 (May 28-31, 1972).					
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Lit. 2	Brandt, L., et al.; A Dowel Insert for Anterior Cervical Interbody Fusion; J. Neurosurg. 61:793-794 (October 1984).
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